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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,182

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Albert J. Banes

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EXAMINER

PERUNGA VOOR, SATHYANARAYA V

ART UNIT

PAPER NUMBER

2624

MAIL DATE

DELIVERY MODE

11/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,182	Applicant(s) BANES ET AL.	
	Examiner SATH V. PERUNGAVOOR	Art Unit 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9, 11, 18-20, 22, 23, 25, 31, 32, 36-39, 41, 43, 44, 46, 53-55, 65-67 and 69-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 October 2009 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-5,7-9,11,18-20,22,23,25,31,32,36-39,41,43,44,46,53-55,65-67 and 69-72.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

[1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 5, 2009 has been entered.

Specification

[2] The specification amendment filed on October 5, 2009 has not been entered because it recites a configuration of the mechanical loading mechanism (i.e. whether the loading mechanism is inside the incubator or outside the incubator) which is not recited in the application as originally filed. Therefore, the amendment is considered to be new matter and not entered.

Drawings

[3] The drawing amendment filed on October 5, 2009 has not been entered because it recites a configuration of the mechanical loading mechanism (i.e. whether the loading mechanism is inside the incubator or outside the incubator) which is not recited in the application as originally filed. Therefore, the amendment is considered to be new matter and not entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[4] Claims 1-5, 7-9, 11, 18-20, 22, 23, 25, 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

- In Claim 1: There is no support in the application as originally filed for the limitation of, “a computer controller configured to (ii) analyze the data for determining at least one of the following: matrix organization, matrix compaction, matrix contraction, response to loading, or any combination thereof”.

[5] Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Limitation claimed in claim 7 is already recited in the independent claim 1.

[6] Claims 36-39, 41, 43, 44, 46, 53-55 and 65-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

- In Claim 36: There is no support in the application as originally filed for the limitation of, “(c) analyzing the three-dimensional image; and (d) determining at least one of the following: matrix organization, matrix compaction, matrix contraction, response to loading, or any combination thereof”.

[7] Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Limitation claimed in claim 38 is already recited in the independent claim 36 in a narrower form.

[8] Claims 69-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

- In Claim 69: There is no support in the application as originally filed for the limitation of, “computing means for receiving and analyzing the three-dimensional data, and determining at least one of the following: matrix organization, matrix compaction, matrix contraction, response to loading, or any combination thereof”

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- In Claim 70: There is no support in the application as originally filed for the limitation of, “a computer controller configured to.... determine a response to a load applied by the mechanical loading mechanism to the tissue engineered construct within the well area of interest”
- In Claim 71: There is no support in the application as originally filed for the limitation of, “(f) determining a response to the applied load”
- In Claim 72: There is no support in the application as originally filed for the limitation of, “determining a response to the applied load”

Contact Information

[9] Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Sath V. Perungavoor whose telephone number is (571) 272-7455. The examiner can normally be reached on Monday to Friday from 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Bhavesh M. Mehta whose telephone number is (571) 272-7453, can be reached on Monday to Friday from 9:00am to 5:00pm. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system,

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see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dated: November 5, 2009

/Sath V. Perungavoor/

Sath V. Perungavoor
Primary Examiner, Art Unit 2624
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